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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,639	04/12/2004	Darryl J. C. Pappin	BP0309US-CP1	1937

23544 7590 03/08/2006

APPLIED BIOSYSTEMS  
500 OLD CONNECTICUT PATH  
FRAMINGHAM, MA 01701

EXAMINER

CORDERO GARCIA, MARCELA M

ART UNIT PAPER NUMBER

1654

DATE MAILED: 03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/822,639

Applicant(s)

PAPPIN ET AL.

Examiner

Marcela M. Cordero Garcia

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7-20 is/are pending in the application.
- 4a) Of the above claim(s) 9-12, 16-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7,8,13-15 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

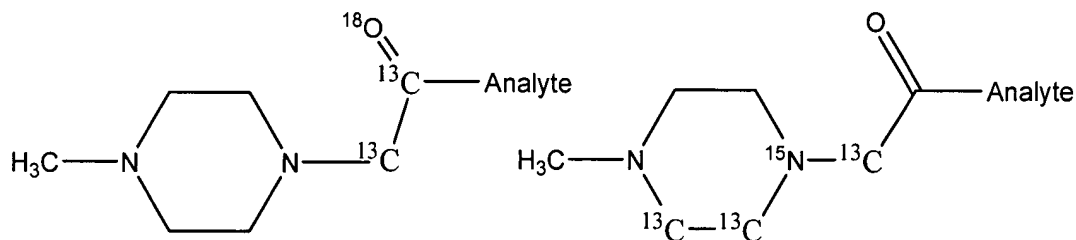
**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/05</u>   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

Claims 7-20 are pending in the application.

Applicant's election without traverse of the species wherein the combination of fragment ions derived from labeled analytes of formula:



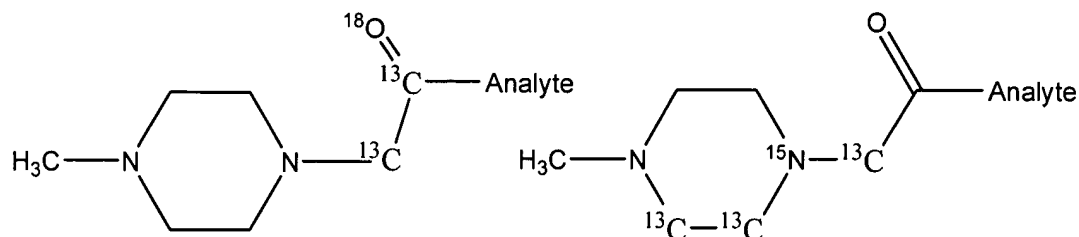
wherein Analyte = peptide, in the reply filed on December 15, 2005 is acknowledged.

Claims 7-9, 13-16, 20 are readable upon the elected species and are presented for examination on the merits

***Claim Rejections - 35 USC § 112***

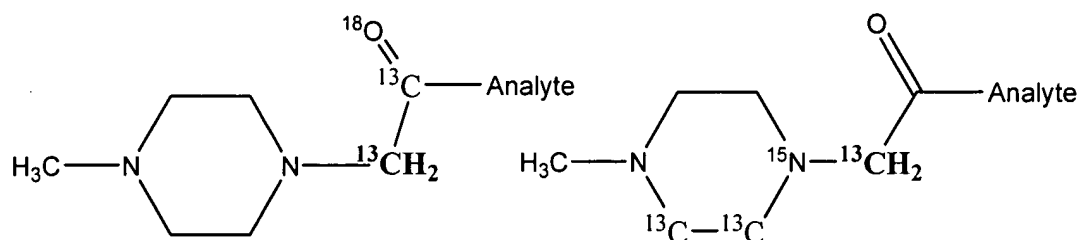
Claims 7-8, 13-15, 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

Claims 7 and 14 are indefinite because they do not have all bonds accounted for in the carbon atom to the right of the piperazine ring, i.e.,



Art Unit: 1654

should instead be, for example:



### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

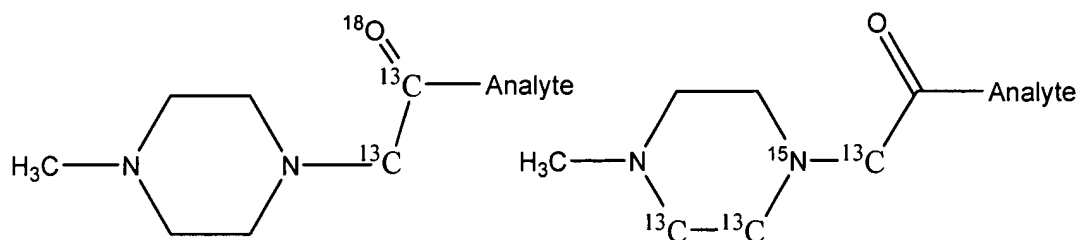
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7-8, 13-15, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lerchen et al. (US 2005/0049406) in view of Shetty et al. (Biomed Mass Spectrom, 1983).

Lerchen et al. teach a mixture comprising fragment ions derived by fragmentation of the same analyte labeled with two or more different isobaric labels, wherein ions of the labeled analytes were selected for fragmentation and further analysis in a tandem mass spectrometer (e.g., claims and [0590]-[0591], [0612]-[0617]). Lerchen et al. teach

Art Unit: 1654

a mixture of compounds comprising piperazine and Analyte = peptide (See, e.g., paragraphs [0006]-[0011] and Examples), however Lerner et al. do not specifically teach the mixture wherein at least two of the labeled analytes are compounds of a formula:



Shetty et al. teach that piperazine compounds produce strong piperazinium ions [CC<sub>5</sub>H<sub>12</sub>N<sub>2</sub><sup>+</sup>] upon tandem mass spectrometry (Step a' in Scheme I).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the mixture of Lerner et al. by using other compounds that generate piperazinium ions [CC<sub>5</sub>H<sub>12</sub>N<sub>2</sub><sup>+</sup>] as taught by Shetty et al. (see, e.g., Scheme I, page 604, column 1). The skilled artisan would have been motivated to do so because of the teachings of Lerner et al. that disclose such compounds as desirable mass taggers for peptides (see, e.g., [0058]). There would have been a reasonable expectation of success, given the fact that such analysis is applicable to a wide range of compounds as taught by Lerner et al. (See, e.g., Example and Figures). The adjustment of particular conventional working conditions (e.g., isotopically labeling the piperazine, selecting the linker to the analyte) is deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan. (See, e.g., paragraphs [0020], [0038]-[0058]). Thus the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7-8, 13-15, 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/999,638. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to fragment ions that encompass the instantly claimed invention. (See, e.g., page 13, lines 3-12 and Figure 5 of Application '638).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 7-8, 13-15, 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 92-105 of copending Application No. 10/765,458. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to fragment ions that encompass the instantly claimed invention. (See, e.g., page 43, lines 2-12 of Application '458).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 7-8, 13-15, 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 92-105 of copending Application No. 10/765,264. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to fragment ions that encompass the instantly claimed invention. (See, e.g., page 31, lines 5-15 and Figure 10 of Application '264).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Art Unit: 1654

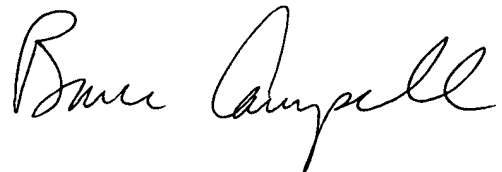
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M. Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marcela M Cordero Garcia, Ph.D.  
Patent Examiner  
Art Unit 1654

MMCG 02/06

A handwritten signature in cursive script, appearing to read "Bruce Campell".

**BRUCE R. CAMPELL, PH.D**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**